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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,227	07/29/2003	Subhas Kundu	A4072.0024/P024-A	4761
24998	7590	06/21/2006	EXAMINER	
DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP 2101 L Street, NW Washington, DC 20037			YEBASSA, DESTA LETTA	
		ART UNIT	PAPER NUMBER	
		1615		

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/628,227	KUNDU ET AL.
	Examiner Desta L. Yebassa	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 13 April 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 154-264 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 154-264 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
     Paper No(s)/Mail Date 11/05/2003.

4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Acknowledgment is made for the information disclosure statement (IDS) filed 10/05/2003. Receipt also acknowledged of the oath or declaration filed on 07/29/2003.

### ***Response to Election/Restriction Amendment***

Rejections of Election/Restriction was withdrawn in view of applicants request and amendment filed on 04/13/2006

### **Claim Rejections - 35 USC § 112**

Claims 154-156 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. About 90 % of the floccules have a diameter of less than 12 to 50 microns, 21-50 microns, and 28 to 50 microns, were claimed in claims 154, 155, and 156 respectively. It is unclear as to what applicants intended to convey by "a diameter of less than 12 to 50, 21 to 50, and 28 to 50 microns". Clarification is required

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 154-156, 161-172 are provisionally rejected under the judicially created doctrine of -obviousness-type double patenting as being unpatentable over claims 1-2, 5, 11-24 of U.S. Patent No 6,656,505. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant claims are drawn to a method for forming an aqueous flocculated suspension of megestrol acetate, comprising of a wetting agent such as polyoxyethylene, docusate sodium; a suspending agent such as polyhydric alcohol, xanthan gum, hydroxypropyl cellulose; and other ingredients including buffer, preservatives. In both US Patent and instant claims an aqueous flocculated suspension contain 40 mg/ml micronized megestrol acetate and about 90 % of the floccules of megestrol acetate that have a diameter of less than 12 to 50 microns. Both patent and instant claims are drawn to methods; the claims of the US patent recite the same specific wetting agent, suspending agent, and other ingredients as in the instant claims. One of ordinary skill would be motivated to use the composition of Patent No 6,656,505 to make an aqueous flocculated suspension of megestrol acetate with the reasonable expectation of success to obtain the best possible result.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

***Claim Rejections - 35 USC § 102***

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 154-156, 161-172, 222-224 and 230-242 are rejected under 35 U.S.C. 102(e) as being anticipated by Ragunathan et al (U.S. Patent No. 6,028,065).

Claims 155-156, 161-162, 164-170 and 172 are depending from claim 154. Claim 163 depends from claim 161 which in turn depends from claim 154. Claim 171 depends from claim 170, which in turn depends from claim 154. Ragunathan et al disclose a pharmaceutical composition in the form of flocculated suspension of megestrol acetate in water comprising of wetting agent, suspending agent, and other ingredients wherein the concentration of megestrol acetate in the flocculated suspension is preferably about 40 mg/ml, and about 90 % of the floccules of megestrol acetate have a diameter between 3.0 to 10 microns (abstract, column 3, lines 25, and column 4, lines 60-65).

Claims 154-156 are clearly anticipated by Ragunathan et al. In the same manner claims 222-224, are anticipated by Ragunathan et al. Ragunathan et al also disclose wetting agents such as docusate sodium comprises of about 0.005 to 0.02 % weight/volum; polyethylene glycol, polypropylene glycol comprises of about 10-25 % weight/volum; suspending agent such as xanthum gum comprises of about 0.15 to 0.25 %

weight/volum; and other ingredients including preservatives such as sodium benzoate; buffers such as citric acid and sodium citrate ( column 5, lines 1-30). Furthermore, Ragunathan et a disclose method and preparation of the composition that involves mixing and homogenizing, detail is demonstrated by examples 1 and 2. See (column 5, table 2, and column 6, table 3). Therefore, claims 161-172 are clearly anticipated by Ragunathan et al. In the same manner claims 230-242 are also anticipated by Ragunathan et al.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 154-156, 162, 165-170, 172-174, 177-179, 182-190, 200-208, 211-213, 216-220, 222-224, 234-242, 245-247, 250-254, and 256-264 are anticipated by Atzinger et al. (U.S. Patent No. 5,338,732).

Claims 155-156, 162, 165-170 and 172 are depending from claim 154. Claim 171 depends from claim 170, which in turn depends from claim 154.

Atzinger et al. disclose a pharmaceutical compositions comprising of micronized megestrol acetate at a concentration of 15 to 150 mg/ml, preferably at 40 mg/ml comprising polysorbate at a concentration of 0.005 % to 0.015 % weight/volume and polyethylene glycol at a concentration of 5-30 % weight/volume in the form of stable

flocculated suspension of megestrol acetate in water (abstract and column 2, lines 35-45). Atzinger et al. also disclose other ingredients used in the composition includes surfactant; wetting agent; protective colloid/ suspending agent such as xanthan gum; preservatives such as sodium benzoate; buffers such as citric acid and sodium citrate; sweeteners such as sucrose; flavoring agent such as lemon lime; excipients and the like wherein the megestrol acetate in the flocculated suspension is about 90 % of the floccules of megestrol acetate have a diameter between 3.0 to 10 microns (column 2, lines 60-65, column 3, lines 5-30, column 4, example 2, table 2 and column 5, example 3, table 3). Claims 154-156, 162, 165-170, 172 and 174 are clearly anticipated by Atzinger et al. In the same manner claims 188-190, 197, 200-208, 222-224, 231, and 234-242 are anticipated by Atzinger et al. Claims 173, 177 and 178 are depending from claim 154. Claims 179 and 182 are depending from claim 178 which in turn depends from claim 154. Claims 183, 185-187 are depending from claims 154. Claim 184 depends from claim 183 which in turn depends from claim 154. Furthermore, Atzinger et al. disclose method and process of the preparation of the megestrol acetate suspension that involves preparation of the components, melting(heating), high shear mixing and homogenizing, cooling, and the like (column 5, lines 25-45). Thus claims 154 , 173, 177-179, and 182-187 are clearly anticipated by Atzinger et al. In the same manner claims 188, 211-213, 216-220, 222, 245-247, 250-254, and 256-264 are anticipated by Atzinger et al.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 154, 157-161, 163-164, 171, 175-176, 180-181, 184, 188, 191-198, 209-210, 214-215, 221, 225-233, 243-244, 248-249 and 255 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragunathan et al (U.S. Patent No. 6,028,065) in view of Koch et al (U.S. Patent No. 5,712,310).

Ragunathan et al. has been discussed above.

Ragunathan et al. does not specifically teach suspending agent such as hydroxylpropyl cellulose (HPC) as claimed. However Koch et al disclose this limitation.

Koch et al disclose water-soluble aqueous suspension which is useful for the delivery of at least one substantially water-insoluble pharmaceutically active agent drugs; suspending agent such as hydroxylpropyl cellulose (HPC), methyl cellulose (MC), hydroxypropyl methyl cellulose (HPMC), microcrystalline cellulose, xanthan gum and wetting agent (column 5, lines 40-55, column 6, lines 55, and column 7, lines 35-

45). Koch et al also disclose method and process for the preparation of the suspension includes the use of (addition of hot and cooling process) by different temperature scale (column 10, lines 20-65). More detail is demonstrated by examples 1 and 4. See (column 11, lines 20-65 and column 12, lines 45-65).

Therefore, it would have been obvious to one of ordinary skill in the art to use the composition of Ragunathan et al for the preparation of aqueous suspension of megestrol acetate comprising of wetting agent, suspending agent, and other ingredients since Koch et al disclose similar composition including stable suspension, non-reactive, cost effective, and furthermore, that overcomes many of the disadvantages that are inherent in suspensions created using substantially water soluble ingredients. One of ordinary skill in the art would be motivated to combine the compositions taught by Ragunathan et al and Koch et al. for the preparation of effective aqueous suspension of megestrol acetate in similar condition with a reasonable expectation of success. The prior art references, as combined teach the limitations of the instant claims. Therefore, the invention as whole has been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

#### **Telephonic Inquiry**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Desta L. Yebassa whose telephone number is 571-272-8511. The examiner can normally be reached on Monday to Friday 8.00 am –6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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